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Attorney Docket No: 7175/67882
PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|-------------|---|-----------|-------------------------------|
| Applicant: | Arthur C. Coffey | Conf. No. | 1909 |
| Serial No.: | 09/855,287 | Art Unit: | 1615 |
| Filed: | May 15, 2001 | Examiner: | Channavajjala, Lakshmi Sarada |
| For: | COMBINATION SIS AND VACUUM BANDAGE AND METHOD | | |

DECLARATION UNDER 37 C.F.R. 1.32

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Arthur C. Coffey do hereby declare that:

I am a medical doctor and have been in surgery training (seven years) and then in active practice of surgery post training for the past six years;

In my surgery practice, I have observed and been involved in both vacuum medicine for treating wounds and collagen bandages for treating wounds. Before my invention thereof, I am not aware of anyone combining these two treatment techniques. The suppliers for each technique stress that the technique works by itself. In the practice, these two techniques are mutually independent.

I am the inventor of the invention described in the above-identified patent application;

That the use of vacuum medicine for treating human wounds was well known before the invention described in the above-identified application as evidenced by the descriptions thereof in that application;

That the use of collagen bandages for treating human wounds was well known before the invention described in the above-identified application, as evidenced by the description thereof in that application;

That the use of collagen bandages provides for a bioabsorbable support matrix on the wound which absorbs exudates from the wound and adheres to and protects the wound while providing limited release of exudates from the wound. (Note U.S. Patent No. 4,841,962 to Berg et al. and U.S. Patent No. 4,754,354 to Quarfoot attached hereto.)

My invention is to use the vacuum to draw the exudates from the wound into the collagen.

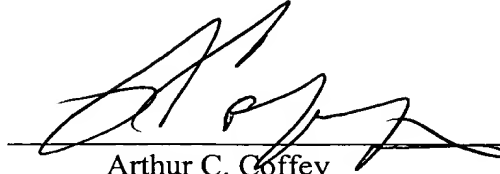
Because (at the time of my invention) the features of adherence to the wound surface to provide the matrix structure for healing and because of the desired limited release of exudates; it was not believed that use of a vacuum system with a collagen bandage would be a good idea since the vacuum system would lift off the collagen matrix from the wound (see page 19 - JUMP-START WOUND HEALING WITH OASIS p. 19 WOUNDS Vol. B No. 2 April 2001 copy attached) and the collagen bandage would be dried out too quickly.

Further declarant sayeth not.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: March 15, 2004


Arthur C. Goffey

Jump-Start Wound Healing with OASIS

Frustrated by hard-to-heal wounds?

This innovative product
gives you more control.

Supported through an unrestricted educational grant from Cook Wound/Ostomy/Continence
and Cook Surgical of Cook Group, Inc.



These practical tips from an array of wound care specialists will ensure treatment efficacy.

When and How TO USE OASIS

DR. NIEZGODA: NOW THAT WE HAVE DISCUSSED the type of wounds that we see in our clinics and our thought processes that guide how we manage those wounds, I think we would be in agreement that if presented with a dried, necrotic, escharred wound, our goal would be to remove that eschar, develop a granulating bed, and then enhance epithelialization, contraction, and wound closure. Considering this scenario, the question is: Where does Oasis fit in to this treatment regimen? Is it first-line therapy? Is it near the end of our therapy? Is it somewhere in between? What is the experience of this group for using Oasis? When is using Oasis appropriate?

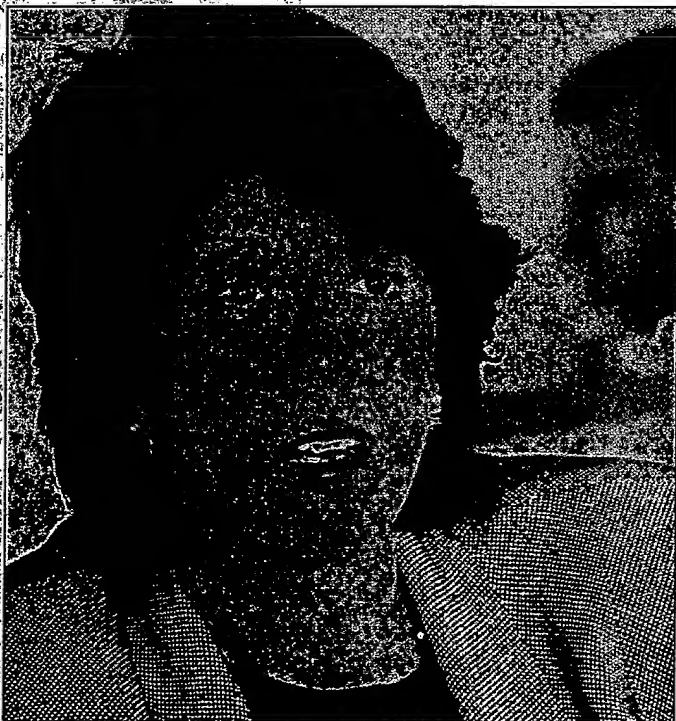
Ms. Brown-Etris: I've been treating patients with Oasis

for about three to four years. A Cook sales rep said to me, "I noticed you use Oasis at a different point than does Dr. Parmenter. Dr. Parmenter will use it at the time of surgery, and you're doing these other things first. Why is that?"

I stopped for a moment and said, "Well, you know, it's because the wounds that I'm applying it to have been in existence for weeks or maybe months. I'm questioning that they are colonized with bacteria. I'm going to use dressings that will clean up my wound base, bring in a granulation tissue, absorb exudate, and be anti-microbial. Once I've done all that, I feel as if I'm giving any dressing the best chance to succeed. And that includes Oasis. Whereas Dr. Parmenter's in the OR. He's doing an amputation, he's debriding down very deeply to healthy tissue—he's removing all of the necrotic debris and unhealthy tissue, so he gets to his nice base more quickly."

Ms. Brown-Etris:

When I used Oasis to treat patients with venous ulcers, their comment when they were healed, which was probably after about eight-weeks, was that it healed a lot faster than when they were treating it before.



Dr. Niezgoda: So your clinical experience is in applying Oasis to healthy, viable tissue?

Ms. Brown-Etris: It doesn't have to be totally healthy but I like a good 80 percent base.

Dr. Niezgoda: But does the wound need to demonstrate reasonable progress towards a granulating bed?

Ms. Brown-Etris: And it could be a wound that's been stagnant with granulation tissue. I have patients come in to my office and say: "Well, I've had this wound for two years and it hasn't changed. My doctor said I should see you and you could close it now."

Ms. Milne: Sometimes when I have a formulary, I have to convince people it's actually cheaper to buy what looks to be a more expensive dressing up front. But, in fact, if you can speed the healing, it is actually a lot cheaper to go out of formulary. I try to keep that in mind, but when I first start using a new product I have a tendency to use it on chronic, non-healing, stalled wounds, just to see how they would go.

Oasis has been very successful in jump-starting a lot of these chronic wounds, and now I'm using it earlier in the wound healing process. I'm still getting very good results.

Dr. Mostow: We've all thrown out this term, "jump-start." I don't want to misguide someone reading this. Would it be appropriate to use a patch of Oasis on a necrotic wound in an attempt to jump-start it?

Dr. Frykberg: No. We're talking about giving these wounds a jump-start. You can have a stalled wound that looks fairly reasonable or you can have a crumbly-looking wound that's got yellow or black eschar that people, unfortunately, do treat with growth factors and everything else and expect it to work. The problem is being able to assess which patients have a reasonable chance of success, because we have to keep in mind that if people start using a product inappropriately, it's not going to work, and they're going to conclude that it doesn't work.

With all these approaches, you cannot supplant the basic tenets of wound care: debridement, proper assessment, treatment of the infection, removing the dry eschar. After all this is done, then as Marie says, it may be possible to jump-start the wounds that look at least 80 percent healthy and viable. But I don't use Oasis initially on a run-of-the-mill ulcer that I see. I want to clean it up

first, and once I see we're starting to get somewhere, then I'll jump-start or expedite healing with Oasis.

Dr. Niezgoda: What, exactly, are we saying? Are we saying jump-start towards epithelialization and toward closure? Is this more appropriate, more realistic of what we're seeing here? The goal is to take the granulating bed to closure. Are we safe to say that when using Oasis, we are jump-starting it to a closure? In my practice, I see how the wound is progressing; if it's clean, viable and healthy then my idea is to jump-start closure by allowing the product to be placed over the wound bed.

Dr. Frykberg: I look at it that way, but I also have another application where I think of the small intestine submucosa product as a biologic dressing. And I remember the old days of the porcine skin graft, which was just laid on the wound, and it provided the right environment to promote healing. Because we're dealing with wounds that have been cleaned, where there's no infection and no sign of ischemia, that just aren't healing with the progress that we want, I will use Oasis at that point to induce a granular bed or to induce some granulation tissue. Let's say you have some exposed tendon or exposed fascia that's not necrotic—it's not dead, but you want to get that covered as quickly as possible—in those cases, I'll use something like Oasis to help stimulate angiogenesis and granulation tissue.

Dr. Niezgoda: So how are we stimulating granulation?

I think we've reached an agreement on where it's appropriate to use Oasis, and we have discussed our philosophy about how this product works, at least why we think it works. Oasis is an extra-cellular matrix. Let's talk a little bit about that. Let's get into more of the biology of wound healing. What is an extra-cellular matrix? Why is this helping us jump-start the wound towards closure?

Ms. Brown-Etris: The extra-cellular matrix, being the submucosa, is essentially feeding the mucosal cells. Oasis is composed of 90 percent water and 10 percent collagen or dry-state collagen, which contains a fraction of carbohydrates and fats. But when you look at it, it's the collagen component, I believe, that is stimulating this cellular regeneration.

It was interesting when we looked at Oasis initially. In the first couple of patients, after about three days, I would get this hole in the Oasis dressing and think to myself,



where is the Oasis? I began following it—no matter how thick I built that Oasis up in layers, in days three or four there was a hole in the dressing. So does that lend credence to the fact that Oasis does incorporate into the tissue and cause cellular regeneration?

Dr. Frykberg: Well, is that the right word? Incorporate into? Is it absorbed? Is it hydrolyzed? Was there a process of enzymatic debridement?

Ms. Brown-Etris: The animal studies show that when Oasis is placed in an area, the cells that are migrating into the area are like cells. This is not only in the wound-care market, but also in the incontinence and the orthopedic areas.

Dr. Frykberg: I agree. I think that's probably the key here. But what we have to be careful about, and I hear people use the term "acellular matrix," is throwing out the words "growth factors." We can't honestly believe that there are active growth factors in there. Have they detected any activity? In fact, I can't believe that a growth factor, which has to be a viable substance, hormone and peptide, is not denatured in the lyophilization process.

Ms. Brown-Etris: When you go camping and you eat freeze-dried foods, does a piece of freeze-dried meat have a protein in it?

Dr. Frykberg: It might have a protein, but it's inactive. Is denatured protein an active biologically active substance? I don't think so. Does it have nutritional value when it's broken down? Yes. But peptides and cytokines are active substances. Growth factors have a life expectancy, if you will. Who else has thoughts?

Dr. Mostow: Dr. Frykberg, I have to echo that. My vision of what Oasis is doing is that it's doing a lot of things that we may not completely understand. However, it's providing a collagen matrix to hopefully stimulate keratinocytes and fibroblasts to produce more collagen, two things we want. We want it to close. We want it to fill. The growth factor issue drove me crazy. The answer is that we don't know. Denaturation is a process that's not complete all the way through. We just need that portion of the protein that acts on the proper receptors, and if we have that then we win. Right?

But we still don't know the answer. It's going back to that jump-start question we were talking about before. If I follow along and the wound is slowing down after it was improving, that's my model for wanting to kick it back in gear. Now the other side of the coin that we've talked

about is that the wound is getting better and it's a race.

The faster we close it, the lower the risk of infection, the lower the risk of amputation, the lower the ultimate cost. As you were saying, you can't be short-sighted in two dressing with different costs. At least this is the case for venous ulcers. I'm curious what you folks are doing in ulcers in other areas. One of the limiting factors it seems to me is that some people can't tolerate a dressing, such as the compression bandages. It's not because they don't have pulses, but because they just physically can't keep a dressing on for three, four or five days. So, we eliminate those people. They tell us it hurts, they're disgusted by it, they refuse to not take a shower, whatever the case might be.

Ms. Brown-Etris: Is it because it's an exudating wound?

Dr. Mostow: There are a million reasons why. I don't know.

Ms. Brown-Etris: When I used Oasis to treat patients with venous ulcers, their comment when they were healed, which was probably after about eight weeks, was that it healed much faster than before. That's a very subjective statement. This is what I'm hearing echoed from individuals.

Looking at the secondary dressing, we've used a composite-type island dressing in the past. Right now I'm using more foams because full thickness would require exudate management. There are also foams that provide a barrier to odor. This then allows that patient to keep the dressing on for a longer period of time. With venous ulcers that are exudative, I'm happy with twice a week dressing changes. A good quality foam on top of Oasis does not adhere to the Oasis thus allowing the Oasis stays in place.

Dr. Niezgoda: Let's hold that thought just for a bit. I want to hear from Dr. Song. What is Oasis? Why do you think it works?

Dr. Song: I do not have a good answer as to how Oasis works on a molecular level. We definitely need more in-depth studies. We have a laser Doppler imager which measures skin perfusion. Using this technique, I have begun to examine the effects of Oasis on cutaneous perfusion in and around the wound. If Oasis does promote angiogenesis, I expect to observe increased cutaneous blood flow to wounds that were treated with Oasis. Regardless of the exact molecular mechanism, I have not

Oasis in a Diabetic Ulcer

personally observed any adverse reactions to Oasis. It's too soon to determine objectively whether Oasis shortens the healing time or minimizes the total cost compared to other modalities. Nevertheless, it does not seem to 'harm' or delay the healing. As with any new product, I was more reluctant to try it on my patients initially. However, given its ease of use, reasonable cost, and favorable experiences thus far, I'm more inclined to try it on any clean wounds with a granulation base.

Dr. Niezgoda: I think that is the bottom line. We don't have all the answers. I was taught that the whole idea is to recruit fibroblasts and other cells to form a collagen matrix, thus stimulating budding angiogenesis, which is followed by epithelialization to cover and close the wound.

Maybe what we're doing is allowing the product to provide the right wound environment and, by stimulating angiogenesis, it's inducing its own growth factors. Maybe there are parts of these proteins in this product that are inactive until placed on the wound. I think these answers will need to be worked out.

Let's talk a little bit more about rejection, infection, and healing times. How does Oasis compare with other products?

Ms. Brown-Etris: The only problem that I've encountered is when I have a wound that has an excessive amount of exudate and I can't get attachment of the dressing, causing it to hydroplane.

Dr. Niezgoda: Do you find that that's better if you use a perforated versus non-perforated sheet?

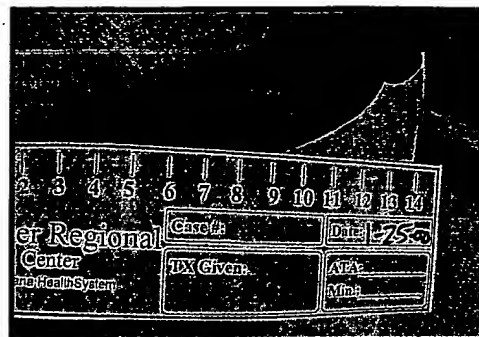
Ms. Brown-Etris: I'm using the perforated.

Ms. Milne: In my experience, it hasn't made a difference.

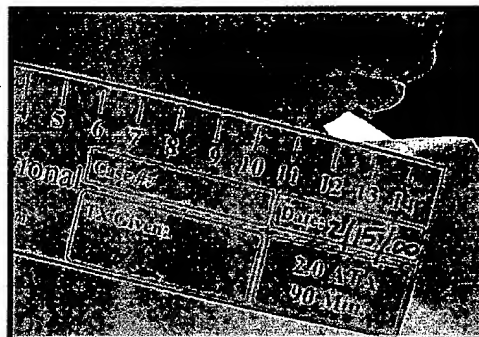
Ms. Brown-Etris: Well, I will say in the early studies, I had my hands on the non-fenestrated. I used to fenestrate it myself, and I felt it made a difference. Then Cook developed a fenestrated version. But recently we've worked worked with the fenestrated.

Dr. Niezgoda: Is the pre-packaged fenestration from the company adequate enough for all wounds? A fenestrated product to meet the needs of every wound is a difficult task. I often create additional fenestrations and find that in heavily draining wounds this makes a difference, by allowing more drainage to

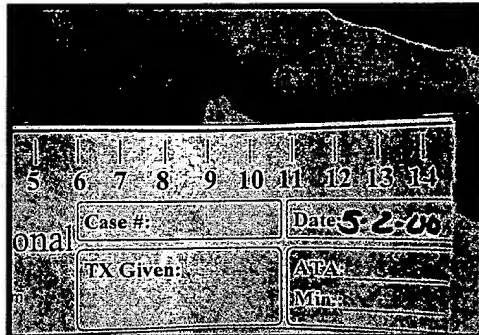
01.25.00. Antibiotics and sharp debridement were used to treat the eschar and surrounding cellulitis.



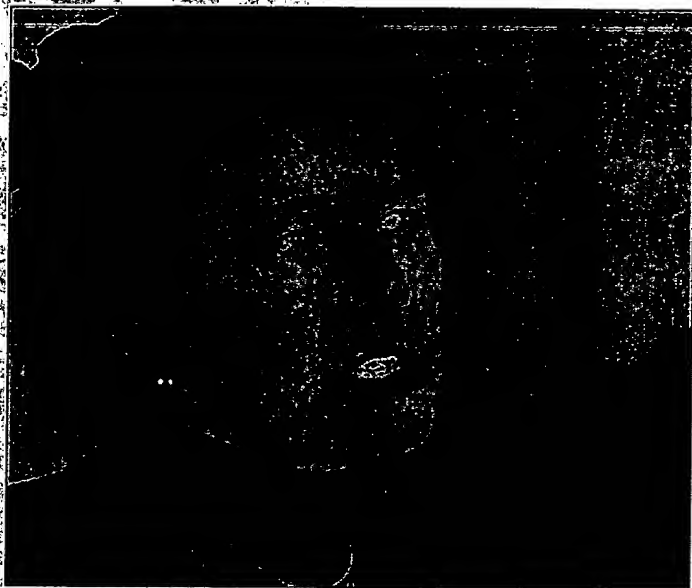
02.15.00. Oasis Wound Dressing was placed over the granulation bed.



05.02.00. Follow-up shows that after 11 weeks of management with the Oasis Wound Dressing the wound was completely epithelialized.



This 89-year-old female patient with insulin-dependent diabetes and Alzheimer's disease presented with an injury to the medial aspect of the first metatarsal that had persisted for three months (01.25.00). The eschar and surrounding cellulitis were treated with IV Rocephin and sharp debridement. Chemical debridement and becaplermin were used for three weeks prior to placement of Oasis Wound Dressing (02.15.00). At that time the ulcer measured 2.5cm x 1.7cm x 0.2cm deep. Some granulation tissue was present, although the extensor tendon remained exposed. A Mepitel dressing covered the Oasis Wound Dressing to help maintain a moist wound environment. The saline-moistened gauze dressing was changed daily. At the end of one week the Mepitel dressing was removed and only saline gauze dressings were used. The tendon was covered with granulation tissue in two weeks and the ulcer was completely epithelialized in 11 weeks.



One patient had a highly exudative venous ulcer.

His showers were a problem because he would wet the lower portion of the secondary dressing. I found that he was getting an excessive amount of maceration in the peri-wound, so I just placed a moisture barrier on the peri-wound area, backed off of the wound, margined a little bit, placed my Oasis on top and he was just fine.

Ms. Milne

pass through.

Has anyone had any problems with risk of infection, irritation, or rashes?

Ms. Brown-Etris: No.

Ms. Milne: No.

Dr. Niezgoda: Pain? Has anyone had any problem with pain?

Ms. Milne: I've had a few people with pressure ulcers that are painful and they do report less pain after the application of the dressing.

Dr. Niezgoda: In our experience, it's a very good dressing for patient comfort and patient satisfaction. Certainly, rejection has not been an issue at all. We have had one patient that did have some erythema that may have been attributed to the Oasis, maybe not. It's hard to sort out. We were using other things, including a barrier product around the wound so it's difficult to say. But overall rejection is not an issue. How about infection? Have you seen any infection problems?

Dr. Song: No, but I think this is, in part, due to our comprehensive wound care strategy as we have previously discussed: proper wound assessment, infection control, disease management, compression therapy in the case of venous stasis ulcers, wound debridement and off-loading in the case of diabetic foot ulcers, local wound care, regular follow-up/evaluation and care, etc.

Dr. Niezgoda: Let's go back to Dr. Frykberg. What is your standard application?

Dr. Frykberg: Depends on the wound. I had a patient

with diabetes and a venous stasis component as well, with a long history of multiple wounds which she caused herself because it's so itchy and scratchy. In that case, I was just putting a piece of Oasis on a fresh excoriated wound of fairly good size, and just covering it directly with an Unna boot just to hide it from her. And much to my surprise and joy, I took the Unna boot off the following week to find the wound was completely dry, completely reepithelialized.

Now, on the diabetic foot ulcers on the plantar surface, of course, it's a different story. You have to pay careful attention to off-loading, because if you let the patient walk on a dressing without off-loading, it's going to shear right off. In those cases, I'm sure I don't do anything different than anybody else, just put the Oasis on, usually over a granular bed. Sometimes, I'll use saline dressing right on the Oasis and I'll just put a secondary dressing on and say, "Leave it alone."

Dr. Mostow: How long are you leaving it on?

Dr. Frykberg: Usually I try to leave it on for seven days. I usually don't even want the patient to touch it.

Another interesting way I've been trying to experiment is using hydrocolloid as a secondary dressing. I'll put on the Oasis, and I might put a saline gauze on or I might just put the Oasis on and cover it with the hydrocolloid to maintain the moist environment. I keep the dressing in place to hide it from the patient. That's a nice,

interesting way to do it.

Ms. Milne: I think you make an excellent point. We don't know the best secondary dressing to use with this product yet.

Dr. Mostow: Which is why I asked; maybe that's a plus. You go with what seems to work.

This I certainly haven't done, but I like the idea. In the beginning I always try the things as they recommend it and see. And I think they were focusing on the foam dressings to cover it. We've had pretty good success. I went back and looked at our first 54 venous patients, and all 54 were people who had tried other things before. Though I can't characterize the sizes, 47 percent of them healed in an average of 28.5 days. Frankly, that's pretty good.

Dr. Milne: That's impressive.

I do see a difference in healing rates based on the secondary dressing. I think more studies need to be done about how we can optimize healing with the appropriate dressings.

Dr. Frykberg: Of course, that's the art issue, isn't it?

Dr. Niezgoda: This goes back to the "art" of wound healing. We need to modify our dressings based on the wound and based on the patient. The product insert says to hydrate the Oasis, then apply it to the wound, cover with Adaptic, place a moistened dressing over the Adaptic, then change the moistened dressing on a daily basis. In my wound care clinic, I often deviate from that quite a bit.

Dr. Frykberg: I won't hydrate it first, so I'm left with a little mush.

Ms. Milne: I like to apply a dry dressing with saline, and then I cover with the secondary dressing.

Dr. Niezgoda: I think it makes intuitive sense that it doesn't really matter whether it's hydrated before it goes on the wound. Oftentimes, the wound is going to drain, which will hydrate the Oasis.

Ms. Brown-Etris: I believe that placing it on dry allows for exudate uptake into the dressing.

Dr. Frykberg: Exactly right.

Dr. Niezgoda: Does anyone here irrigate or spray saline on the wound?

Ms. Brown-Etris: I cleanse the wound with saline, and then I don't dry the wound.

Ms. Milne: Right.

Dr. Mostow: How are you folks dealing with the decu-

bitus ulcers, which are going to be much more concave than perhaps many of our other ulcers? Are you doing a big bolster in there to hold it down?

Ms. Brown-Etris: It's a matter of lining the wound bed, then applying secondary dressing.

Dr. Mostow: Even on diabetic feet you're making contact and then on top you're not looking to necessarily bolster it down?

Dr. Frykberg: That's not my sense with this dressing. I agree that the dry dressing sticks on the ulcer better. And although we're perhaps doing some similar things, it seems that that appearance is not as crucial to get things closing.

Dr. Niezgoda: Dr. Frykberg has suggested applying Duoderm right over the top. Are there any other thoughts on other applications, other than the standard Adaptic on top of the Oasis before applying the secondary dressing?

Dr. Frykberg: I just put the Oasis on. I'm a renegade. I use betadine and I don't care. I like Betadine for non-crumby wounds. I'll even put betadine on the wound because I feel better, even though I'm not supposed to. I use Iodosorb too. Just putting the Unna-boot on is a different way to go, with no dressing over the Oasis other than the Unna-boot.

Dr. Niezgoda: I was just about to bring up the topic of compression. We'll put the Oasis down and just put the Viscopaste right over the top of it. That seems to work pretty nicely.

Dr. Mostow: We've really moved away from the unna-boot. Instead, we use these multilayer compression bandages.

Ms. Brown-Etris: It depends on the amount of exudate. If I have a lot, I have to use multi-layer dressings.

Ms. Brown-Etris: I'm using re-usable dressings. I happen to really enjoy the Sure-press type product, because then if I need to do a daily dressing change because it's highly exudative, I can, which brings the cost down. I also like it because my patients who do their own dressing changes at home can reapply the Sure-press.

Dr. Niezgoda: One of the other things that we've done is to apply a hydrogel secondary dressing that is changed every day. On our donor skin graft sites, we have found that it's difficult to apply Oasis immediately. Usually, I'll change the standard post-operative dressing on post-op day one. A little bit of homeostasis has been achieved, and



then we apply the Oasis. What we have started to do is apply Oasis, then Adaptic, and then we impregnate a saline soaked gauze with hydrogel and place that over the top. The Hydrogel seems to maintain the moisture a little longer.

Ms. Brown-Etris: In our clinical study on pressure ulcers, we're combining Oasis with saline gel and covering with a secondary dressing. We decided to take the standard of care, fluid normal dressing, and move to a different level. We're using a saline gel that has extended the wear time to 48 to 72 hours, which decreases the nursing time involved.

Ms. Milne: We're not using Adaptic either.

Ms. Brown-Etris: We're simply using Oasis. We have a choice, and it depends on our call at the time of wound assessment. We apply the Oasis. We may want to use the saline gel impregnated gauze and then cover it with the secondary composite dressing, or we might take the gel, and just place it on top to hydrate the Oasis, and then apply the Alldress. So, it can be either way.

Dr. Frykberg: How often are you re-applying the Oasis?

Ms. Brown-Etris: I like to base that decision on how the wound appears. What we're observing is that when we return to evaluate the wound, the core is missing in the Oasis.

Dr. Frykberg: When the core is missing, you just reapply it. I like the idea of maintaining the moisture level in the wound, providing it's not a suppurative wound, which is critical. It used to get me nervous. I've been trying to use bio-occlusive or the semi-permeable membranes as well, trying to keep the moisture in.

Ms. Brown-Etris: The Alldress that we're using in the study has a transparent film incorporated into the dressing itself, so it does just that.

Dr. Frykberg: I really use a well moisturized or saturated gauze pad with saline and gel and put that on and then use these polyurethane membranes to maintain that moisture level for as long as I can underneath that.

Dr. Niezgoda: When you take the secondary dressing off for the first time, what is the Oasis going to look like? We talked about seeing the central area of the dressing gone. What are the different faces of Oasis, and what can you expect to find?

Ms. Milne: Usually at day three or four.

Dr. Niezgoda: What else might you see?

Dr. Frykberg: Dry. Very dry.

Dr. Niezgoda: So with the dry appearance, what do you do? Where are you likely to see the Oasis product dry?

Dr. Frykberg: I've been leaving it there on the wound for acute leg wounds. I like to get dry wounds, or at least a covering where it's not getting a lot of drainage, and I leave it there. Then I might put my compression back on. I don't know whether I should or I shouldn't, but my instinct is to just leave it alone.

Dr. Niezgoda: That's what we've been doing, too! On smaller wounds—I'm talking about 2 or 3cm—we'll just leave it. I'll just continue to monitor the patient, allowing the Oasis to be dry.

Ms. Brown-Etris: What do you mean when you say dry?

Dr. Frykberg: I'm talking about that scab, that pre-schar that will separate, leaving the healed wound underneath.

Dr. Mostow: That's right. With no drainage from underneath the wound.

Dr. Frykberg: And that seems to be what happens. It just separates and you have a healed wound over it.

Dr. Niezgoda: Concerning the patient that comes in having a periphery of intact Oasis with kind of a caramelized base with a central portion. What do you do to that patient? How do you re-apply?

Dr. Mostow: I tend to trim away the outer material because I don't like extra debris in the periphery. So that part is dry. And then if the central part looks moist enough and looks like it's completely clear, we put on another piece.

It comes back to this whole question, since we don't completely understand what it's doing. I try to keep working with the medical students and the residents on a model they can understand. I say, you know, you get this dry wound, no exudate, no matter what we're using. I tell them that's not an environment where keratinocytes or skin cells can migrate.

Ms. Milne: If I still see it in the wound, I'll touch it. And if it's adherent I'll leave it alone. If it's movable I take it off.

Dr. Mostow: I agree with you there. I don't spend extra money if I don't need to spend extra money.

Ms. Brown-Etris: And I tend not to trim the periphery. In fact, in the beginning I can remember paying attention to their directions on cutting to size. After a while I quit worrying about it.

When I use larger pieces, I can find the dressing. If I can't see it on the wound and it's really compressed down and adherent to the surrounding skin, I can always bring my gloved fingernail along and give a little scrape. If I can pick up the edge, it's there. And then I'll leave it be. I can identify now.

Dr. Niezgoda: How about draining wounds that we would typically use some sort of barrier agent to protect the peri-wound environment? Is anyone in the group using a barrier cream with the Oasis application?

Ms. Milne: Yes, I did that, and it made a big difference. The patient had a highly exudative venous ulcer. His showers were a problem because he would wet the lower portion of the secondary dressing. I found that he was getting an excessive amount of maceration in the peri-wound, so I just placed a moisture barrier on the peri-wound area, backed off of the wound, margined a little bit, placed my Oasis on top and he was just fine.

Dr. Niezgoda: When you apply a peri-wound moisture barrier, the resulting stickiness that you have around the wound, enhances the application because the Oasis sticks down very nicely. The Oasis doesn't shift and slide and it stays where you put it, especially when it is hydrated.

Ms. Milne: In the overly wet wound, the Oasis will just hydroplane. That's a clue to me that I need to add a calcium alginate or do something differently to get better adherence.

Dr. Frykberg

Another interesting way I've been trying to experiment is using hydrocolloid as a secondary dressing. I'll put on the Oasis, and I might put a saline gauze on or I might just put the Oasis on and cover it with the hydrocolloid to maintain the moist environment.

Dr. Song: I also tend to not trim the periphery. My general practice is to use a larger piece of Oasis to completely cover the borders of the wound. I wet the Oasis on gauze and then apply it to the wound. If the wound is exudative, I apply a little moisture barrier around the wound and add absorbent foam to the secondary dressing. On the following visit, I try to remove the excess Oasis, beyond the wound edges, by gently pulling it. Sometimes, I use pressurized (8 psi) wash saline to facilitate this. If Oasis from the central portion comes off with the excess, I will remove it. But, in general, I don't make an effort to remove Oasis from the wound. I do not want to interrupt the healing process.

Dr. Frykberg: I use Oasis in conjunction with VAC. I'll typically use the VAC when I have a heavily exudative wound or a deep wound and if I just want to get things prepared. I never thought about using it under the VAC because I think the negative pressure is going to suck it off. I've used becalpermin gel to prepare a wound bed, and then use this in conjunction with it. I try to be flexible with what I do.

Ms. Brown-Etris: We have a patient who was on VAC, progressed very nicely on it, and then just hit a point





where she plateaued. At that point, we entered her on the study. She was randomized to the Oasis group and immediately her wound bumped, started kicking back in again. Now she's probably at week 10 and we're using a miniscule piece on her wound. It just resumed the healing process after it had plateaued.

Dr. Niezgoda: I use VAC extensively to prepare wounds. Once the wound is granulated and healthy and clean, we usually transition to a different type of primary dressing.

I really have been working closer with my plastic surgeons, vascular surgeons, and general surgeons, and I've earned almost universal acceptance of post-operative VAC on skin grafts. It works great for anybody with a compromised graft.

Dr. Mostow: That's one of the indications, is it not?

Dr. Niezgoda: We had a patient with a compromised wound that had a skin graft. We did our standard post-operative VAC, took the VAC off, and the graft looked great except for one of the margins. So I took some Oasis, put the Oasis down, covered the entire area with

AdepteC and put the VAC back on. This patient did really well.

Ms. Brown-Etris: How did that look? You piqued my interest. When you next removed the dressing, how did that Oasis appear, as far as with the graft? Could you see lines of demarcation? Or was there some type of integration?

Dr. Niezgoda: It was very nice—the appearance was not unlike what you'd see when you took off another secondary dressing. As far as the VAC pulling the Oasis away, well, it doesn't pull the skin graft so it's not going to pull the Oasis away. It looked very much as you would expect. The only difference was that the caramelized central area wasn't there. The appearance was very uniform. Some of the Oasis was actually overlying the graft. This area looked very healthy and pliable too.

Ms. Milne: Do you think there's a role for combining your skin graft and your Oasis to get a better take?

Dr. Niezgoda: We haven't done that. I think it's a very interesting idea, and I would love to try it. I think that it would be prudent to do some work in the animal first before we try this on a patient.

Ms. Milne: I've been using Oasis in wounds that you typically would have considered for grafting.

Dr. Frykberg: I think that is the concept you really want in this case. While it is not a bi-layer epidermis product, it is a biological dressing, and we're not hoping for a graft take, but something to really stimulate this more than we can do with our other dressings, right?

Dr. Song

I have not personally observed any adverse reactions to Oasis.

Given its ease of use, reasonable cost, and favorable experience this far, I'm inclined to try Oasis on any clean wounds with a granulation base.



Additional Uses for Oasis

Ms. Brown-Etris: Right.

I had a patient who fell while she was making her bed. She tripped on the corner of her sheet and fell on her leg. She is a heavy woman, and she just destroyed the tissue on her lower leg. She went to the hospital, orthopedic surgery was involved, and literally she had full thickness tissue involvement from her knee almost to her ankle and circumferential medial to lateral and anterior. Posterior was intact. And when I saw her a month after this trauma, her medial aspect was granulating slightly, but she still had a full thickness eschar on the lateral aspect, which I then debrided. I eventually put her on Oasis, with much involvement from both my patient and her husband. They're both physicians and that's why they had called me out.

It's just amazing to see the healing response from Oasis. She's been on steroids for 20 years. She's now taking between 5-10mg a day. She has rheumatoid arthritis. She has so many factors that are just deterrents to good wound healing. And I have to look at the tissue now that has healed and say, it's pretty amazing to me that this wound, which was quite extensive, has healed with minimal scarring. I'm pleasantly surprised.

Dr. Niezgoda: Your point, again, is very well taken. Our job is to get the wounds to heal and use whatever tools are required to heal them. And I am a firm believer in the philosophy that there is no one tool out there that is going to heal all wounds.

We have been experimenting with combining growth factors with Oasis. We have our patients apply it topically with their dressing changes, and we've had some very good results. I'm not going to argue with success. I think that this tool is a good tool by itself, but I think there is plenty of room for expanding its role and our scope of use. ■

Dr. Niezgoda: Is anyone using Oasis for applications other than those we've discussed?

Dr. Frykberg: I've used Oasis for surgical wounds and laser wounds. With the CO₂ laser you create an acute ulcer. There's a lot of things that we just haven't experimented with that we can, such as wounds from punch biopsy.

Dr. Mostow: Dermatologists do a lot of transverse removals. For certain skin cancers, we do shave biopsies or treat with electro-dessication and curettage, which is a fancy scraping and burning. A big skin cancer might take a month to heal secondarily—and people get used to it. But maybe I can change this with Oasis.

Ms. Brown-Etris: What if you used it with a Mohs procedure?

Dr. Mostow: Well, most Mohs surgeons, at least in our area, will close those wounds, although in some areas of the country they still have people do it secondarily. And in some areas of the body, that's okay. So there are arguments where maybe you would enhance it by doing this, such as in cavities near the nose and the leg.

Ms. Brown-Etris: Well, I'd be curious about that because a year ago I had a small skin excision and I have a divot-like scar on my arm today. When I'm assessing full thickness wounds on which I've used Oasis, and I see this beautiful scarring with very level skin, I think, "Why couldn't my little wound heal this nicely?"

Dr. Mostow: I do a moderate number of flaps. Where a flap may necrose, to be able to jump in there right away with something that might enhance that healing and reduce scarring makes a lot of sense.

Dr. Frykberg: Has anybody ever implanted Oasis?

I'm thinking of when I had to debride an old chronic wound with osteomyelitis, and you have a half surgical wound and half open center that I typically will allow to granulate for several weeks. I'm just sitting here thinking, wouldn't it have been nice to just lay some Oasis on the wound underneath my suturing, so that I've got a protective coating that's going to generate more rapid healing?

Dr. Niezgoda: Even those patients that are not necessarily considered compromised from a healing standpoint can benefit from Oasis either from a pain standpoint or closure standpoint.

I have found Oasis to be an excellent part of my armamentarium for wound healing. It has to be applied in the right setting, under the right conditions, and when the wound is ready for the Oasis, I think Oasis accelerates the healing process very nicely. It's cost-effective and offers excellent comfort and pain control. It's not the answer to healing all wounds, but I certainly think it should be a tool for every good wound care practitioner.

Dr. Frykberg: I think if you use this product in the appropriate wound, recognizing the fact that it does not supplant good attention to wound care tenets, that it can help to expedite the healing of chronic wounds much more so than standard care. I think it's exciting because we still don't know all the uses.